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Registration Decision

RD2014-27

Acetic Acid

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Registration Decision for White Vinegar 12% Technical

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of White Vinegar 12% Technical and White Vinegar 12%, containing the technical grade active ingredient acetic acid, for the control of perennial weeds in cranberry crop.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2014-15, *Acetic Acid*. This Registration Decision² describes this stage of the PMRA's regulatory process for Acetic Acid and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2014-15. This decision is consistent with the proposed registration decision stated in PRD2014-15.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-15, *Acetic Acid* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Acetic Acid?

Acetic acid (CH_3COOH) is a molecule composed of carbon (C), hydrogen (H) and oxygen (O_2). It is an organic acid that is readily biodegradable into non-toxic substances such as carbon dioxide (CO_2) and water (H_2O). Acetic acid acts as a non-selective contact herbicide. When it comes into contact with any parts of the plant, the acid quickly destroys the cell membrane, causing desiccation of the foliar tissues and ultimately killing the plant.

White Vinegar 12% is a new liquid herbicide containing 12% acetic acid. The product consists of non-synthetic acetic acid, which is naturally present in food-grade white vinegar. White Vinegar 12% contains no surfactants or adjuvants, making it suitable for both conventional and organic cranberry production.

Health Considerations

Can Approved Uses of Acetic Acid Affect Human Health?

Acetic Acid is unlikely to affect human health when used according to label directions.

Exposure to acetic acid at 12 % (v/v) may occur when handling the end-use product, White Vinegar 12%, such as during mixing, loading or applying the product, or during clean up and maintenance activities. People entering areas treated with acetic acid are not likely to be exposed since the product is applied directly into the soil. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, containing acetic acid, is expected to be of low toxicity by the oral and inhalation routes. Based on the low pH of the solution, it is expected to be slightly acutely toxic by the dermal route, mildly irritating to the respiratory tract, and mildly to moderately irritating to the skin. It is corrosive to the eyes, and is not likely to be a skin sensitizer.

Exposure to humans from the commercial use of the end-use product, White Vinegar 12%, is not expected to be of concern due to the precautionary statements present on the end-use product label that are aimed at mitigating exposure.

Residues in Water and Food

Dietary risks on food and water are not of health concern.

The end-use product, White Vinegar 12%, is injected into the soil surrounding cranberry plants and is not applied directly to food. In soil, acetic acid is expected to degrade rapidly. Also, the end-use product label has precautionary statements not to contaminate food, feed, and water with the end-use product; therefore, dietary exposure to acetic acid from the registered use is anticipated to be negligible. The PMRA has determined that a maximum residue limit (MRL) is not required for White Vinegar 12%.

No risk due to exposure from drinking water is anticipated as acetic acid is unlikely to persist in the environment to the extent that it could be consumed in drinking water.

Occupational Risks From Handling White Vinegar 12%

Occupational risks are not of concern when White Vinegar 12% is used according to label directions, which include precautionary statements.

White Vinegar 12% is to be applied by commercial applicators who will inject the product directly into the soil surrounding cranberry plants with a specially-designed injection tool.

Occupational exposure to individuals handling White Vinegar 12% is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary statements (for example, wearing of personal protective equipment) and hygiene statements on the label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Acetic Acid is Introduced Into the Environment?

White Vinegar 12% is registered for control of perennial weeds in cranberry fields by injection into the soil at the root system level. Due to the nature of the registered use and the known properties of acetic acid, the potential for exposure of non-target terrestrial and aquatic organisms to White Vinegar 12% is expected to be low. Therefore, the risk associated with the use of this product at the registered application rates and use pattern is expected to be negligible.

Value Considerations

What Is the Value of White Vinegar 12% Herbicide?

An application of White Vinegar 12% by injection into the soil can control perennial weeds that form tillers or compact tufts, such as plants in the Gramineae, Cyperaceae (Scirpus and Carex) and Juncaceae families, in cranberry production, including organic production.

White Vinegar 12% has shown efficacy against target weeds such as grasses, sedges, bulrushes and rushes. Pre-emergence herbicides registered for use in cranberry production cannot control biennial plants or established perennials. Acetic acid could serve as a complementary treatment or an alternative to the large-scale application of sprout inhibitors. Since White Vinegar 12% is used in localized applications, it could help to reduce the use of conventional herbicides.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures registered on the label of White Vinegar 12% to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The signal words "CAUTION– SKIN IRRITANT" and "DANGER – CORROSIVE TO EYES" are required on the principal display panels of both the technical product and the end-use product label.

Standard hazard and precautionary statements are also required on both the technical and end-use product labels to inform workers of the irritation potential of the active ingredient and to caution that it is corrosive to eyes and that it causes irritation when inhaled or absorbed through the skin.

Based on the hazard profile (for example, corrosive to eyes, likely to irritate skin and the respiratory tract), standard personal protective equipment are required for workers handling the product, for example, long clothing, shoes and socks, chemical resistant gloves, and protective eyewear.

A precautionary statement on the end-use product label indicating that handling of the end-use product (including the clean-up and maintenance activities) should be performed in a well-ventilated area is required.

Label statements advising individuals not to allow contact of the product with skin, eyes or clothing and to avoid breathing vapours or spray mist are also required.

Based on the method of application of the product (soil injection), a restricted-entry interval is not required.

The end-use product label instructs that workers not contaminate food or feed.

Value

White Vinegar 12% can serve as a complementary treatment or an alternative to the large-scale application of sprout inhibitors. Furthermore, it can be applied to localized areas and thereby reduce the use of conventional herbicides.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-15, *Acetic Acid*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.